DETAILED ACTION

Response to Amendment

This office action is responsive to the preliminary amendment filed on October 16, 2006. As directed by the amendment: claims 1, 5, and 17 have been amended, claim 4 has been canceled, and no new claims have been added. Thus, claims 1-3 and 20 are presently pending in the application.

Claim Objections

1. Claim 1, 12, and 13 are objected to because of the following informalities: In claim 1, lines 3, 4, 5, 8, and 10, there are periods in the middle of the claim. Similarly, claim 12 and 13 contain periods in the middle of the claim. Periods should only be placed at the end of a claim except for use in abbreviations (see MPEP 608.01 (m)). Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 7 and 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP

§ 2172.01. The omitted structural cooperative relationships are: a structural relationship between the structure of the device and the piston. The claim recites "measurement of a piston displacement rate" but does not recite any structural elements which include a piston.

5. Claims 9-16 are rejected based on their dependency to rejected claim 7.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, 3, 5, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (US Patent No. 4,765,325).

8. As to claim 1 and 3, Crutchfield discloses a method for fit testing a respirator 10 having a breathing port 24, comprising the steps of: placing the respirator 10 on a test subject's face (col. 4, ln. 7-9), having the test subject hold his breath (col. 4, ln. 27), closing a breathing port 24 of said respirator 10 (col. 4, ln. 27-30), thereby initiating a controlled negative pressure testing protocol when intra-respirator pressure substantially equals ambient pressure (since Crutchfield's method comprises having the patient exhale (creating a positive pressure inside the respirator) and then subsequently applying a vacuum to create a negative pressure within the respirator, it is inherent that the pressure within the respirator would have to be equal to ambient pressure at some

point during this time period), producing and maintaining a predetermined level of vacuum in the respirator 10 (col. 4, ln. 30-41), and measuring a flow rate of air necessary to maintain said level of vacuum (col. 5, ln. 4-12). Crutchfield lacks detailed description as to the limitation that closing of the breathing port is activated by a switch which is activated by the test subject. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the respirator of Crutchfield to include a switch to activate closing of the valve 42 to close off the breathing port 24 since switches are well known in the art for activating valves and it appears that Crutchfield's method would perform equally well with the inclusion of a switch to close the breathing port. Furthermore, having the test subject activate the switch is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to have to test subject activate the switch in order to reduce the number of people required to perform the test since it appears Crutchfield's method would perform equally well with the test subject activating the switch to close the breathing port.

9. As to claim 2, Crutchfield discloses that the test subject inhales before holding his breath (col. 4, ln. 11-12).

10. As to claim 5, Crutchfield discloses monitoring internal respirator pressure (via pressure transducer 32 (Fig. 3, col. 8, ln. 13-18).

11. As to claim 17, The modified apparatus of Crutchfield discloses the claimed invention (as discussed in claim 1 above) including a leak rate analyzer (Fig. 3)

comprising an air-pressure transducer 32, a vacuum source 38, an air-flow measuring device 30.

12. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of DuBois (US Patent No. 3,948,589).

13. As to claim 6, Crutchfield discloses the claimed invention except that the breathing port is closed by generating an air pressure sufficient to move a diaphragm within the breathing port into an air-sealing position. However, DuBois teaches the use of a squeeze bulb 94 to generate a pressure sufficient to move a diaphragm 72 (col. 5, ln. 41-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include closing the port by generating a pressure sufficient to move a diaphragm as taught by DuBois in order to provide a suitable means for manually controlling opening and closing of breathing port since it appears that Crutchfield's method would perform equally well with this modification.

14. As to claim 8, the modified method of Crutchfield discloses that release of the switch results in the opening of the breathing port (see col. 5, ln. 54-60 of DuBois).

15. Claims 7 and 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Spinello (US Patent Publication 2003/0100888).

16. As to claim 7, Crutchfield discloses exhausting air from the respirator (via vacuum) to generate and maintain a desired negative challenge pressure inside the respirator for a specified test period, whereby the challenge pressure is held constant

(col. 4, ln. 30-41), but does not disclose that measurement of a piston displacement rate yields a direct measure of an air leakage rate into the respirator. However, Spinello teaches measuring a flow rate based on displacement of the piston (paragraph [0050]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include measurement of a piston displacement to yield the air leakage rate as taught by Spinello, in order to provide an accurate and easy means for measuring the leakage rate since it appears that Crutchfield's method would perform equally well with this modification.

17. As to claim 9, the modified method of Crutchfield discloses that internal respirator pressure is progressively reduced to the negative challenge pressure in order to limit challenge pressure overshoot (col. 4, ln. 30-41 of Crutchfield).

18. As to claim 10-16, the modified method of Crutchfield discloses the claimed invention including a vacuum source 38 (Fig. 3), but does not disclose adjusting a motor control logic of the vacuum source according to the claimed iterative algorithm. However, choosing an algorithm for control of a motor is a design consideration and it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include the iterative algorithm in order provide a suitable means for controlling the performance of the vacuum source since it appears that Cruthchfield's method would perform equally well with this modification.

19. As to claim 12, the modified method of Crutchfield discloses the claimed invention except for storing pressure and leak flow rate information in an array during a track phase of the fit test; and applying a post-test analysis algorithm to integrate all

acceptable leak measurements while excluding those segments of the track phase that do not meet predetermined pressure criteria or identifying periods or bins of acceptable pressure tracking, determining whether an acceptable number of such bins was produced during the fit test; and integrating the flow rate measurements associated with each bin to determine the mean respirator leak rate for that specific test, wherein test quality is quantified as a function of the number of acceptable pressure bins recorded during the fit test, said function comprises: if bins > 3, then report measured leak rate; else if 3 > bins > 0, then report estimated leak rate; else if bins = 0, then report retry test, and wherein said specified range of said challenge pressure comprises + 10%. However, choosing a method for analyzing post-test data is a design consideration. Furthermore, taking acceptable values of a test run and integrating the measurements to get a mean value is a well known procedure for evaluating the performance of a test. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Crutchfield to include the steps of analyzing the data post-testing in order to evaluate the overall performance of the test since it appears that Crutchfield's method would perform equally well with a post-test analysis.

20. Claims 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield, in view of Zocca et al. (US Patent Publication 2003/0172925).

21. Crutchfield discloses the claimed invention including a by-pass orifice 52 present in tubing 54 between the vacuum source and the leak rate analyzer (col. 9, ln. 37-40), but lacks detailed description as to the limitation that the air-flow measuring device and

said vacuum source comprise a piston controlled by a stepper motor. However, Zocca teaches a piston 244 (Fig. 12c) used in a vacuum source that is controlled by a stepper motor 247 (paragraph [0118], ln. 1-14). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a stepper motor controlled piston as the vacuum source in order to provide a suitable means for pumping air out of the respirator since it appears that Crutchfield's apparatus would perform equally well with a stepper motor controlled piston as the means for withdrawing air from the inside of the mask.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Willeke (US 4,846,166) and Osendorf et al. (US 5,647,356).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALERIE SKORUPA whose telephone number is (571)270-1479. The examiner can normally be reached on Monday - Friday, 8:00 a.m. - 5:00 p.m., EST, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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